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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/419,611	10/18/1999	HIROSHI IZUI	0010-1045-0	1525

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/419,611	IZUI ET AL.	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6-14,16 and 28-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-14,16 and 28-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 October 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/19/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 2, 6-14, 16, 28-33 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 2, 6-10, 16, 18, and 20-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed 03/07/2005 have been fully considered but they are not persuasive. The examiner respectfully disagrees with applicants position that the claim amendments, the reference of Eikmanns et al., and the BLASTN search attached to the amendment show that applicants had possession of the claimed invention.

In the evaluation of the claims for compliance with the written description requirement of 35 U.S.C. 112, of particular relevance is 66 FR 1099, Friday, January 5, 2001,which states:

> "*Eli Lilly* explains that a chemical compound's name does not necessarily convey a written description of the named chemical compound, particularly when a genus of compounds is claimed. *Eli Lilly,* 119 F.3d at 1568, 43 USPQ2d at 1405. The name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. *Eli Lilly,* 119 F.3d at 1568, 43 USPQ2d at 1406. Thus *Eli Lilly*

identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed." (see p. 1100, 1st column, line 47 to 2nd column, line 2).

The claims are genus claims that are directed toward a genus of genes of any nucleotide sequence encoding any citrate synthase of any amino acid sequence obtained from *Corynebacterium glutamicum* or *Brevibacterium lactofermentum* including all mutants and variants thereof.

The recitation of the name "citrate synthase gene" does not define any structural features and nucleotides sequences commonly possessed by the genus. Furthermore, the specification does not describe and define any structural features and nucleotide sequences commonly possessed by the genus including all mutants and variants thereof. Thus, one skilled in the art cannot visualize or recognize the identity of the members of the genus.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v, Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. Therefore, the instant claims are not adequately described.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of a genus of genes of any nucleotide sequence encoding any citrate synthase of any amino acid sequence obtained from *Corynebacterium glutamicum* or *Brevibacterium lactofermentum* including all mutants and variants thereof.

Furthermore, a review of the specification indicates that elements which are not particularly described, including regulatory elements, promoters, enhancers, and untranslated regions, are essential to the function of the claimed invention because the claims recite a "citrate synthase gene". The art indicates that the structure of genes with regulatory elements and

untranslated regions is empirically determined. Therefore, the structure of these elements which applicants considers as being essential to the function of the claim are not conventional in the art.

There is no known or disclosed correlation between an isolated nucleic acid encoding a citrate synthase and the structure of the non-described elements of the gene. Furthermore, there is no additional disclosure of physical and/or chemical properties for these non-described elements. In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of the genus of citrate synthase genes.

Claim Rejections - 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 2, 6-9, 16, 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skillman et al. (Microbiology. 1998 Aug;144 (Pt 8):2095-101) in view of Eikmanns et al. (Microbiology. 1994 Aug;140 (Pt 8):1817-28).

Skillman et al. teach *enterobacter agglomerans* strain transformed with a plasmid encoding green fluorescent protein (GFP) (see entire publication). Skillman et al. does not teach that the *enterobacter agglomerans* strain is transformed with a citrate synthase gene from *Corynebacterium glutamicum* or *Brevibacterium lactofermentum.*

Eikmanns et al. teach the nucleotide sequence of the gltA gene of *Corynebacterium glutamicum.* The enclosed printout from the NCBI Taxonomy Browser shows that *Brevibacterium lactofermentum* is a synonym for *Corynebacterium glutamicum.*

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the *enterobacter agglomerans* strain taught by Skillman et al. such that instead of being transformed with a plasmid encoding GFP, the gltA gene of *Corynebacterium glutamicum* taught by Eikmanns et al. is transformed into the said the *enterobacter agglomerans* strain. One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to obtain a transformed *enterobacter*

agglomerans that can be used in a process to express and purify the citrate synthase of *Corynebacterium glutamicum.*

In regard to claim 16, the claim is a product by process claim where no patentable weight is given to the process of obtaining the citrate synthase gene using the recited PCR primers. Thus, the gltA gene of *Corynebacterium glutamicum* of Eikmanns et al. teaches the citrate synthase gene of claim 16.

6. Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skillman et al. (Microbiology. 1998 Aug;144 (Pt 8):2095-101) in view of Eikmanns et al. (Microbiology. 1994 Aug;140 (Pt 8):1817-28) as applied to claim 1, 2, 6-9, 16, 28-32 above; and further in view of JP63214189 (Mikio et al.; ABSTRACT).

JP63214189 (Mikio et al.) teach a process for producing L-glutamic acid comprising culturing coryneform bacterium in a liquid medium to produce and accumulate L-glutamic acid (see abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the process taught by JP63214189 such that the coryneform bacterium is replaced with the modified *enterobacter agglomerans* strain taught by Skillman et al. having the gltA gene of *Corynebacterium glutamicum* taught by Eikmanns et al. stated above. One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to have a fermentation process to make L-glutamic acid and as an alternative to a chemical synthesis of L-glutamic acid.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N

Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

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